EXHIBIT 34

EXPERT REPORT, ANNA LEMBKE, M.D.

March 25, 2019

MDL No. 2804

Relating to Case Nos. 17-OP-45004 and 18-OP-45090

A. Background and Qualification

1. I am an Associate Professor, Chief of the Addiction Medicine Dual Diagnosis Clinic, Medical Director of Addiction Medicine, and Program Director of the Addiction Medicine Fellowship, in the Department of Psychiatry and Behavioral Sciences at Stanford University School of Medicine. Since 2016, I also hold a Courtesy Appointment in the Stanford University Department of Anesthesiology and Pain Medicine. I began my faculty career at Stanford in 2003. A true copy of my current CV is attached to this Report as Exhibit A.

2. I received my undergraduate degree in Humanities from Yale University in 1989, and my medical degree from Stanford University in 1995, where I also completed a partial residency in Pathology (1997) and a full residency in Psychiatry (2000), as well as a Fellowship in Mood Disorders, Department of Psychiatry and Behavioral Sciences (2002).

3. I have been licensed to practice medicine in the State of California from 1995 to the present. I received the DEA-X waiver to prescribe buprenorphine products in 2013. I am a diplomate of the American Board of Psychiatry and Neurology (2003; recertified, 2013), and a diplomate of the American Board of Addiction Medicine (2013).

4. From 2001 to the present, I have taught medical students, residents, and fellows at Stanford University School of Medicine, on a diversity of topics related to psychiatry, addiction, and pain. For example, from 2004 to the present, I have given annual lectures on addiction medicine within the Practice of Medicine (POM) series for Stanford medical students, including topics such as the neurobiology of addiction, how doctors should intervene when they detect substance use problems, and how to have difficult conversations with patients on the topic of substance use, misuse, overuse, and addiction.

5. I received the Stanford Award for Excellence in Academic Teaching, Department of Psychiatry, in 2014, and again in 2018.

6. As a full time faculty at the Stanford University School of Medicine, I regularly treat patients with addiction to opioids and other substances. For the last 15 years, my clinical practice has included a significant proportion of patients taking prescription opioids for pain relief, for whom such drugs have resulted in misuse, dependence, and addiction. As an integral part of my practice, I work with these patients to develop treatment plans that will address their pain while making appropriate efforts to reduce (taper) or eliminate use of opioids, and/or treat their opioid addiction. Such plans can include non-opioid medications for pain, as well as alternative, non-pharmaceutical modalities, and counseling, with a dual focus on treating the underlying painful condition and the substance use disorder. I also see patients within the Stanford Pain Clinic, where I provide expert consultation in pain and addiction.

7. In 2015, I received the Stanford Chairman's Award for Clinical Innovation for developing inpatient and outpatient clinical services dedicated to helping people with substance use problems.

8. In January 2015 I was appointed by Governor Jerry Brown to the Research Advisory Panel of California. I served on the Panel until 2017. I, along with the other Panel members, was tasked with assessing the safety of clinical trials to be conducted in the state of

California using controlled substances, such as opioids. In this capacity, I applied my knowledge and experience to the review of study designs and protocols, and I made recommendations for procedures to protect patients in these trials, including, in particular, protection from potential harmful effects of opioids.

9. Since 2015 I have served on the Board of the California Society of Addiction Medicine (CSAM). I have been a member of CSAM, and the American Society of Addiction Medicine (ASAM), since 2011.

10. In 2016 I chaired the Planning Committee for the California Society of Addiction Medicine (CSAM) Annual Addiction Medicine Conference.

11. In 2016, I became president of the Addiction Medicine Fellowship Directors Association (AMFDA).

12. In 2016 I led a program funded by the Stanford Center for Continuing Medical Education (SCCME), titled, "Tapering Patients off of Chronic Opioid Therapy."[1]

13. Since 2016, I have chaired the Addiction Medicine Task Force, Stanford University School of Medicine. The goal of the Task Force is to re-evaluate and re-create the medical school curriculum on addiction and safe prescribing of addictive substances. I have served as MedScholar Advisor on the topic of *Developing the Addiction Curriculum at Stanford*, Stanford University School of Medicine.

14. I am the author of a book on the prescription drug epidemic: "Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop" (Johns Hopkins University Press, October 2016).[2]

15. I have published over 50 peer-reviewed articles, chapters, and commentaries, which have appeared in the New England Journal of Medicine, Journal of the American Medical Association, Pain Medicine, Journal of General Internal Medicine, Addiction, and other peer reviewed journals. Many of these publications address the diagnosis and treatment of addiction, as well as the treatment of pain. I have also published articles on the importance of teaching addiction medicine in medical school, residency, and fellowship, (as discussed in this report).

16. In 2016 I co-authored a peer-reviewed article, "Weighing the Risks and Benefits of Chronic Opioid Therapy," American Family Physician 2016; 93:982-990, which addressed issues of opioid misuse and addiction, risk assessment and mitigation, patient education, tapering to reduce or end opioid exposure, tolerance, dependence, and risks of overdose.[3] American Family Physician is among the most read family physician peer reviewed journals. The readership includes 32,000 medical students and over 3,700 nurse practitioner and physician assistant subscribers.

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[1] https://med.stanford.edu/cme/courses/online/opioid-taper.html

[2] Lembke A. *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*. 1st ed. Johns Hopkins University Press; 2016

[3] Lembke A, Humphreys K, Newmark J. Weighing the risks and benefits of chronic opioid therapy. *Am Fam Physician*. 2016; in press

17. In 2016 I co-authored a Research Letter, JAMA Intern Medicine 2016;176(2):259-261, which examined Medicare data on opioid drug prescription patterns. Our analysis concluded that opioid prescribing is "a widespread practice relatively indifferent to individual physicians, specialty or region. High-volume prescribers are not alone responsible for the high national volume of opioid prescriptions. Efforts to curtail national opioid overprescribing must address a broad swath of prescribers to be effective." [4](pp. 260-261) This article has been cited 71 times in the 3 years since its publication, and has helped to counter the notion that the epidemic of opioid drug misuse and addiction is primarily attributable to a small group of "pill mill" doctors.

18. In 2016 I co-authored a Research Letter, JAMA Psychiatry, 2016;73(9), on the high exposure to opioids among Medicare patients, the growing incidence of opioid use disorder in this population, and the lack of buprenorphine prescribers in this population, noting the gap between the need for treatment, and access to that treatment.[5]

19. In 2018 I co-authored two articles in peer-reviewed pain journals on pain management of patients with chronic pain and opioid use disorder.[6,7]

20. I have testified before the United States House of Representatives on the opioid epidemic and possible means to mitigate harms caused by that epidemic, and I have presented at numerous conferences before governmental, professional, academic and lay audiences on related topics.

21. In forming the opinions expressed in this Report, I have relied on my medical training, more than twenty years of clinical experience, and my own research on opioid prescribing. My research began circa 2001 and has been multimodal. I have done qualitative interviews with patients, providers, and others in the health care field on questions related to opioid prescribing. I have followed and analyzed the medical literature using PubMed and other academic search engines, along with different combinations of key words such as "pain, opioids, treatment, randomized clinical trials, open label trials, effectiveness, adverse effects, prescribing, addiction, dependence, overdose, etc. …" I have compiled statistics published by the CDC and other government agencies. I have, in collaboration with colleagues, analyzed opioid prescribing databases such as Medicare Part D.[8,9] As a regular and ongoing part of my practice, I conduct literature searches of research on the subjects of addiction and pain treatment, which is essential

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[4] Chen JH, Humphreys K, Shah NH, Lembke A. Distribution of opioids by different types of medicare prescribers. *JAMA Intern Med*. December 2015:1-3. http://dx.doi.org/10.1001/jamainternmed.2015.6662, at pp. 260-261.

[5] Lembke A, Chen JH. Use of opioid agonist therapy for medicare patients in 2013. *JAMA Psychiatry*. 2016;73(9). doi:10.1001/jamapsychiatry.2016.1390

[6] Harrison TK, Kornfeld H, Aggarwal AK, Lembke A. Perioperative Considerations for the Patient with Opioid Use Disorder on Buprenorphine, Methadone, or Naltrexone Maintenance Therapy. *Anesthesiol Clin*. 2018;36(3):345-359. doi:10.1016/j.anclin.2018.04.002

[7] Lembke A, Ottestad E, Schmiesing C. Patients Maintained on Buprenorphine for Opioid Use Disorder Should Continue Buprenorphine Through the Perioperative Period. *Pain Med*. 2018;(February):1-4. doi:10.1093/pm/pny019

[8] Chen et.al, "Distribution of Opioids," fn. 4, above, at p. 259

[9] Lembke, *et al.*, "Use of Opioid Agonist Therapy," fn. 5, above, at p. 990

to my work with my patients. Indeed, given the large and increasing role of opioid drugs in addiction, the fields of addiction and pain medicine are inevitably intertwined, such that it is essential to my practice to remain aware of the state of scientific inquiry in both fields. Specifically for this Report, I have considered the materials listed on Exhibit B, attached. I hold the opinions stated in this Report to a reasonable degree of scientific certainty.

22. A statement of my testimony within the last 4 years is attached as Exhibit C and a statement of my compensation rate for consulting work is attached as Exhibit D.

B. Opinions

For the reasons set forth in detail in this Report, I hold the following opinions:

1. Addiction is a chronic, relapsing and remitting disease with a behavioral component, characterized by neuroadaptive brain changes resulting from exposure to addictive drugs. Every human being has the potential to become addicted. Some are more vulnerable than others. Risks for becoming addicted include genetic, developmental, and environmental factors (nature, nurture, and neighborhood). One of the biggest risk factors for addiction is simple access to addictive drugs. Prescription opioids are as addictive as heroin, and the Defendants' conduct in promoting widespread access to prescription opioids has inevitably resulted in an epidemic of opioid addiction.

2. Opioid prescribing began to increase in the 1980's, and became prolific in the 1990's and the early part of the 21st century, creating more access to opioids across the U.S. population, and representing a radical paradigm shift in the treatment of pain. Prior to 1980, doctors prescribed opioid pain relievers sparingly, out of appropriate concern that their patients would get addicted, and then only for short term use in cases of severe injury, surgery, or at the very end of life.

3. The Pharmaceutical Opioid Industry increased sales of prescription opioids, by directly targeting doctors, by promoting key opinion leaders, by infiltrating continuing medical education courses, by supporting professional medical societies, and by co-opting medical watchdog organizations like The Joint Commission, to convince prescribers that liberal opioid prescribing is based on science. In fact there has never been sufficient evidence to justify widespread opioid prescribing.

4. The Pharmaceutical Opioid Industry encouraged and promoted several misconceptions concerning opioid use, including the following:

   a. overstatement of benefits of long-term use for chronic pain. In fact, there is not, and has never been, reliable evidence that long-term opioid use improves pain or function to any clinically meaningful degree. The best evidence available shows that there is little or no improvement in pain or function for most patients on long-term opioid therapy. Patients often endorse ongoing subjective benefit from the opioid, not because it is treating underlying pain, but because it is relieving opioid withdrawal from the previous dose. Studies show that pain improves when patients on chronic high dose opioid therapy reduce their dose or come off opioids.

prescription was continued (30.5%) than those in which an opioid was newly prescribed (22.7%).[26]

v. As reported in an article I co-authored in 2016, more than one-third of Part D Medicare enrollees fill at least one opioid prescription in any given year. Part D covers 68% of the roughly 55 million people on Medicare.[27] As such, more than 10 million Part D Medicare enrollees are exposed to a prescription opioid in any given year, thus becoming vulnerable to the adverse effects of opioids, including but not limited to addiction. Medicare represents just one patient population, suggesting that many millions of patient consumers in this country have been exposed to the risks of prescription opioids in recent decades, both within and outside the Medicare-eligible populations. As discussed later in this report, much of that exposure resulted from aggressive marketing that overstated benefits and downplayed risks of chronic exposure to prescription opioids.

c. As reported in another article I co-authored in 2016, increased opioid prescribing is distributed across different types of prescribers, relatively indifferent to individual physicians, specialty or region.[28] In other words, opioid overprescribing is not the result of a small subset of so-called 'pill mill' doctors, although such doctors do exist, but rather has been driven by a wholesale shift in medical practice. All doctors across diverse medical specialties are prescribing more opioids.

i. By specialty, pain doctors prescribe more opioids than doctors in any other specialties. However, by volume, family medicine and internal medicine doctors account for the most opioids, simply because there are more of them.[29]

ii. But the salient finding was that opioid prescribing is not driven by a minority of prolific prescribers.[30]

d. Although national average opioid prescribing has plateaued or decreased since its peak in 2012, there are still many cities, counties, and states across the nation where opioid prescribing continues to be high, and overall opioid prescribing in the US remains at levels far exceeding pre-1990 rates.

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[26] Sherry TB, Sabety A, Maestas N. Documented Pain Diagnoses in Adults Prescribed Opioids: Results From the National Ambulatory Medical Care Survey, 2006–2015. *Ann Intern Med*. 2018;169(12):892-894, at p. 892.
[27] Lembke *et al.*, "Use of Opioid Agonist Therapy", fn. 5, above, at pp. 990-991.
[28] Chen et.al, "Distribution of Opioids", fn 4, above, at p. E2.
[29] *Id.* at pp. E1-E2.
[30] *Id.* at p. E2.

iv. I have personally experienced this CME strategy. For example, in 2001, every licensed physician in the state of California was mandated to attend a day-long CME course on the treatment of pain as a requirement to maintain licensure. I attended that day-long course, in which use of opioids was promoted. I recall that there was no accurate presentation of the risks of opioids, and the messages that were provided tracked the misconceptions described above regarding overstatement of the benefits of opioids.

v. Consistent with and supportive of my personal experience, Dr. Joel Saper, a past board member of the American Pain Society (APS), testified that "the educational programs of AAPM [American Academy of Pain Management] and APS particularly as they involve opioid advocacy, were greatly influenced by commercial largess. In my opinion, commercial dynamics influenced, if not steered, the selection of abstracts, course topics, and faculty to commercially friendly participants as it involved opioid advocacy, largely ignoring those imposing or exhorting caution against the growing advocacy for opioids for chronic nonmalignant pain.[49] Dr. Saper testified that such educational programs of AAPM and APS involving opioid advocacy were "inappropriate"[50] , and I agree.

vi. Dr. Saper further stated that "APS and AAPM and its members have participated, if not promoted, this crisis by failing to assure the presentation of unbiased, balanced educational programs and guideline development, thereby protecting the public from commercial influence through undisclosed support from the opioid industry. In failing to do so, the organizations failed to protect patients."[51]

vii. Further, an internal Purdue Pharma email from Richard Sackler to Paul Goldenheim, dated April 13, 2001, concerned a planned meeting with "leaders of APS, APF [American Pain Foundation] and other pain societies." Dr. Sackler stated, "Our goal is to bind these organizations more closely to us than heretofore, but also to align them with our expanded mission and to see that the fate of our product(s) are [sic] inextricably bound up with the trajectory of the pain movement."[52]

viii. The use of "Speakers Bureaus" of doctors, trained by a drug company to promote its product, is an adjunct to the CME strategy.

[49] Deposition of Joel R. Saper, M.D., January 11, 2019, MDL No. 2804, at 92:13-22.
[50] *Id.* at 93:15-19.
[51] *Id.* at 115:24-116:6
[52] PPLPC045000004928- PPLPC045000004933 at 4929.

Anna Lembke, M.D. Report

APPENDIX I

I.A: Purdue Pharma

I.B: Mallinckrodt

I.C: Janssen

I.D: Endo Pharmaceuticals

I.E: Allergan

Anna Lembke, M.D.

Appendix I.A.: Purdue Pharma

Purdue Misleading Messaging

A. Benefits of Opioids Not Supported by Reliable Scientific Evidence

1. "Opioids are effective for chronic pain"

- "[W]e now know that many patients with chronic, nonmalignant pain respond very well to opioids and that, contrary to our teaching, addiction is very rare and possibly nonexistent as a result of treating such patients with opioids. The barriers to vastly improved treatment for hundreds of thousands of people in pain, are simply the misinformation and prejudice of doctors, pharmacists and regulatory bodies." Purdue Physicians' Pain Management Speaker Training Program, April 18-20, 1997. PKY181654940-PKY181654982 at 4966.

  Comment: This quote summarizes the essential message promoted initially by Purdue and subsequently by other opioid sellers: that opioids are effective for chronic pain, and that "addiction is very rare and possibly nonexistent," as a result of such treatment. With some variation, the promotional messages detailed in this appendix follow those two themes. As to the claim of efficacy for chronic pain, there was not then, and there has never been, reliable evidence to support the claim (Report, Section C4); as to the assertion of "rare" addiction risk with opioid therapy, there were numerous studies that had reported a range of addiction as high as 24% before the opioid sellers began the aggressive marketing campaign that omitted any reference to those data, and numerous additional, subsequent studies consistent with the earlier results, (Report at section C5).

- "Opioid analgesics are indicated for moderate to severe pain that cannot be relieved with other agents. Opioids are effective, easily titrated, and have a favorable benefit-to-risk ratio. Large doses of opioids may be needed to control pain if it is severe, and extended courses may be necessary if the pain is chronic. Tolerance and physical dependence are normal physiologic consequences of extended opioid therapy and must not be confused with addiction. Patients and family members must be educated regarding the difference between tolerance, physical dependence, and addiction. Patients with chronic, severe pain must not consider themselves addicts because they are being treated with opioids. Concerns about addiction should not prevent the appropriate use of opioids. McPhee JS, Schroeder SA. In Lange's Current Medical Diagnosis Treatment, 1996 p 13." Purdue Physicians' Pain Management Speaker Training Program, April 18-20, 1997. PKY181654940-PKY181654982 at 4969.